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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/756,125	01/12/2004	Dennis R. Burton	48503-00004	3579

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EXAMINER

CHEN, STACY BROWN

ART UNIT

PAPER NUMBER

1648

DATE MAILED: 12/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/756,125

Applicant(s)

BURTON ET AL.

Examiner

Stacy B. Chen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,9-17,19-22,28-36,38-42,47-55,57-60,66-74,76-79,85-93 and 95 is/are pending in the application.
- 4a) Of the above claim(s) 11-14,30-33,49-52,68-71 and 87-90 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,10,15,19-22,29,34,38-41,47,48,57-60,66,67,72-74,76-79,85,86,91-93 and 95 is/are rejected.
- 7) ☒ Claim(s) 9,16,17,28,35,36 and 53-55 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>9/10/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's election with traverse of Group I is acknowledged and entered. Claims 1-3, 9-17, 19-22, 28-36, 38-42, 47-55, 57-60, 66-74, 76-79, 85-93 and 95 are pending. Applicant's traversal has been carefully considered. Applicant argues that the inventions in claims 77 and 91 are also drawn to the elected invention of Group I. In response to this argument, the examiner will include the inventions of claims 77 and 91 (and dependent product claims) in the examination of Group I. Therefore, the restriction is deemed proper and made FINAL.

2. Claims 11-14, 30-33, 42, 49-52, 68-71 and 87-90 are withdrawn from consideration being drawn to non-elected inventions. (Note that claim 42 belongs in the group drawn to nucleic acids. This was an error in the restriction requirement.) Claims 1-3, 9, 10, 15-17, 19-22, 28, 29, 34-36, 38-41, 47, 48, 53-55, 57-60, 66, 67, 72-74, 76-79, 91-93 and 95 are under examination.

Specification

3. The specification is objected to for containing embedded hyperlinks on at least pages 16, 18, 19 and 53, which is impermissible and requires deletion. The attempt to incorporate subject matter into the patent application by reference to a hyperlink and/or other forms of browser-executable code is considered to be an improper incorporation by reference. See MPEP 608.01(p), paragraph I regarding incorporation by reference. Appropriate correction is required.

Claim Objections

4. Claims 1-3, 9, 10, 15-17, 19-22, 28, 29, 34-36, 38-41, 47, 48, 53-55, 57-60, 66, 67, 72-74, 76-79, 91-93 and 95 are objected to for reciting non-elected subject matter.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3, 10, 15, 19-22, 29, 34, 38-41, 47-48, 57-60, 66-67, 72-74, 76, 85, 86, 91-93

and 95 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- Claims 1-3, 19, 20-22, 38-41, 57-60, 76-79 and 95 recite, “At least one isolated mammalian anti-Dengue virus antibody”, or similar language. The scope of the claimed invention is unclear. This type of language, “at least one” is not appropriate in the preamble, rather the body of the claim. (See compositions claim 9, for example.) Suggested language is, “An isolated antibody”.
- Claims 10, 29, 48, 67 and 86 recite, “an effective amount of at least one compound or protein”. It is unclear what the compound or protein is effective for. The claim must indicate that the compound or protein is effective for a particular activity, such as inducing an immune response.
- Claims 15, 29, 34, 48, 53, 67, 72 and 86 recite improper Markush group language. Correct language is found in claim 91, “selected from the group consisting of...and...”
- Claims 19, 38, 57 and 95 are dependent on cancelled claims. The metes and bounds of the claims cannot be determined. Correction is required.

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- Claims 58-60, 66, 67, 72-74 and 76 are drawn to antibodies and compositions/devices containing the antibodies, wherein, “the antibody binds to the same region of a Dengue virus protein as an antibody comprising at least one light chain CDR having the amino acid sequence of at least SEQ ID NO: 4.” It is unclear what protein of the Dengue virus is bound by the antibody comprising SEQ ID NO: 4. It is also unclear what portion (epitope) of said protein is bound by the antibody comprising SEQ ID NO: 4. Clarification is required.
- Claims 77-79 and 91-93 are drawn to antibodies. Claim 77 recites, “At least one isolated mammalian anti-Dengue virus antibody, comprising at least one human CDR, wherein said antibody specifically binds at least one epitope comprising at least at least 1-3 amino acids, to the entire amino acid sequence of a Dengue virus NS protein”. It is unclear what this claim is encompassing. Is the epitope on the NS protein “at least 1-3 amino acids”? If so, it is not clear how an epitope can be comprised of one amino acid. Clarification is required.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 77-79, 85-86, 91-93 and 95 are rejected under 35 U.S.C. 102(b) as being anticipated by Valdés *et al.* (*Clinical and Diagnostic Laboratory Immunology*, 2000, 7(5):856-

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857, "Valdés"). The claims are drawn to isolated antibodies, compositions, medical devices and articles of manufacture for pharmaceutical or diagnostic use. The antibodies specifically bind at least one epitope comprising at least 1-3 amino acids of the Dengue NS protein, specifically the NS1 protein. The compositions further comprise other compounds or proteins, such as labels, NSAIDS, sedatives, antimicrobials, immunoglobulins and others. The medical devices are comprised of the antibodies and are suitable for a variety of modes of delivery. The article of manufacture for human pharmaceutical or diagnostic use comprises the antibodies, packaging material and a container. The antibody has a human CDR. Claim 95 is drawn to an anti-Dengue virus antibody produced by a method according to cancelled claim 94. While this claim is indefinite, the broadest interpretation of the claim has been used, and thus claim 95 is included in this rejection for purposes of compact prosecution.

Valdés discloses human Dengue antibodies against structural and nonstructural proteins, including antibodies against NS1 (abstract). The antibodies were isolated from patients infected with Dengue virus. These antibodies are human and therefore contain human CDRs. It is entirely expected that the antibodies against NS1 bind an epitope that is at least 1-3 amino acids in length, if not longer. With regard to the limitation that the composition comprises at least a pharmaceutically acceptable carrier or diluent (claim 85), the serum samples taken from the patients were diluted during the Western blot analysis of the antibodies (page 856, second column, first paragraph). Performing a Western blot analysis is, according to Valdés, the classical method. In order to perform the Western blot analysis of the human antibodies, several steps are involved which read on the claimed invention. After the antibodies are diluted according to Valdés, they are placed into a syringe with which the diluted solution containing the

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antibodies is injected into the electrophoresis gel sandwiched between glass plates prior to running the current through the gels. With regard to the limitation that the composition further comprises another compound or protein, the dilution of antibodies during the Western blot process reads on the claim (claim 86). The antibody solution that is prepared for Western blot contains more than one antibody (immunoglobulin), thus reading on the claim. The syringe with which the antibody solution is injected into the electrophoresis gel is useful for diagnostic uses and medical devices in non-human animals and can be administered in a variety of ways, such as those listed in claim 91. The syringe itself is a container and packaging material (plastic or glass tube with the syringe and a plastic plunger). Note that the medical devices and articles of manufacture are for uses that are indented but not necessary (“device is suitable”, “an article of manufacture for human pharmaceutical or diagnostic use”). Given the broadest reasonable interpretation of the claims, Valdés anticipates the claimed invention.

Conclusion

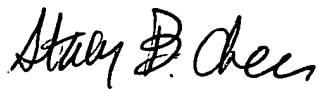
7. No claim is allowed. Claims 9, 16, 17, 28, 35, 36 and 53-55 are objected to for containing non-elected subject matter and for depending from rejected claims. These claims are rejected. The amino acid sequence represented in SEQ ID NO: 4 is free of the prior art of record.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James C. Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

A handwritten signature in black ink that reads "Stacy B. Chen". The signature is written in a cursive, flowing style.

Stacy B. Chen
December 2, 2005